

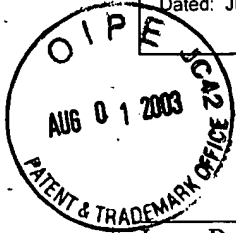
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Dated: July 28, 2003

Signature: *Diane Blevins*

Diane Blevins

17/ Reg for
Release
7-28-03
Docket No.: 273012011700
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Rubinah K. CHOWDHARY and David DOLPHIN

Application No.: 09/851,606

Group Art Unit: 1615

Filed: May 8, 2001

Examiner: G. Kishore

For: SUPPORTS FOR PHOTSENSITIZER
FORMULATIONS

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RESPONSE TO ADVISORY ACTION UNDER 37 CFR 1.116

TECH CENTER 1600/2900

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is responsive to the Advisory Action mailed June 24, 2003 and the "final" Office Action mailed March 27, 2003 which set an initial response deadline of June 27, 2003. Accordingly, a one month extension of time until Sunday, July 27, 2003 is enclosed herewith.

As an initial matter, Applicants thank Examiner Kishore for the courtesy of a telephonic discussion on July 28, 2003 concerning the status of the instant application and the indication of no entry of the response filed June 2, 2003 (mailed May 27, 2003) in the Advisory Action. In light of Examiner Kishore's request for a written response to the Advisory Action, Applicants offer the following.

Contrary to the indication of the response of June 2, 2003 as raising new issues, and despite the pendency of claims 1-30, Applicants respectfully point out that claims 1 and 26 were not amended. Only claim 29 was amended and so Applicants respectfully request reconsideration of entry of the response filed June 2, 2003 (mailed May 27, 2003). Additionally, Applicants request reconsideration in light of the following remarks.

With the entry of the amendment to claim 29, Applicants believe that the rejections thereof under 35 USC § 102 should be reconsidered and withdrawn. Claim 29 remains directed to a method of preparing a composition comprising a mixture of at least one photosensitizer dissolved in at least one carrier agent in liquid form wherein said mixture is combined with at least one solid support *not soluble in said carrier agent* to form said composition. The composition is a precursor formulation that can be used to form liposomes upon hydration.

Applicants also believe that based upon the above discussion, a brief review of the disclosed and claimed invention would be helpful at this point. As noted on page 3, lines 27-29, “the compositions and methods [of the invention] are directed to the association of a precursor formulation containing a photosensitizer and a carrier agent with at least one solid support material.” Moreover, page 4, lines 2-6 state that

“Subsequent addition of an aqueous based medium rapidly hydrates the precursor formulation to produce a formulation containing complexes of photosensitizer and carrier agent. These complexes may be of any form, including (but not limited to), stable micelles, emulsions, gels, matrices, transition phases between the defined states, vesicles or other carrier forms suitable for use in photodynamic therapy.”

Therefore, the pending claims are directed to a combination of a precursor formulation (or “mixture”, as recited in claims 1 and 29) of photosensitizer and carrier agent, capable of forming the complexes described above, with a solid support. This combination, after solidification, is capable of forming said complexes upon hydration. The use of some carrier agents, such as block

copolymers capable of forming micelles (as noted in Kataoka et al.¹, of record in the instant application), permits the "mixture" to contain little or no other agents necessary to form micelles or another complex. Alternatively, the use of one or more additional agents necessary to form said complexes is readily permitted by their presence in the "mixture" as noted on page 6, lines 16-22 of the instant specification.

In light of the above, Applicants respectfully request the reconsideration of all rejections of claim 29 as well as the other pending claims. In particular, Applicants respectfully submit that in light of the amendments and remarks, claims 1-30 may be allowed and the application moved toward issuance. The Examiner is encouraged to contact the undersigned if he determines that further discussions would prove useful.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012011700.

Dated:

Respectfully submitted,

By 

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¹ *J. Controlled Med.* 24:119-132, 1993. Although Kataoka et al. describe the formation of micelles by block copolymers on pages 121-123, they do not teach, suggest, or otherwise indicate the ability of block copolymers to potentially form micelles in the presence of another material, such as a photosensitizer. To the contrary, they only disclose micelle formation by use of the block copolymer PEO/PASP conjugated to adriamycin via a specific linkage where "micelle formation is mainly driven through hydrophobicity and the cohesive force of the conjugated drug itself" (see page 123, right column). This clearly indicates that even Kataoka et al. do not envision the use of block copolymers as forming micelles capable of containing adriamycin in the absence of the conjugation.